

EXHIBIT “B”

From: David Opperman <dopper@firstriskadvisors.com>
Sent: Friday, May 14, 2021 12:41 PM
To: Light, Janice Catherine <jcl4@psu.edu>; Mc Naughton, Christopher <cxm790@psu.edu>
Cc: Kara Opperman <kopperman@firstriskadvisors.com>
Subject: 2021-2020 Treatment Coverage

Good Afternoon Janice/Christopher,

At this time the review for pre-determination of benefits for the 2021-2022 with UnitedHealthcare StudentResources is complete and a decision has been rendered. Kara and I have worked closely with the United team in order to make sure this situation received a full review and determination.

I did want to take a minute to again outline the process we went through in making this determination.

United Healthcare manages infusion drugs for safety, efficacy and cost management and the drug criteria may change frequently for a variety of different reasons. Changes to drug policies are made on a frequent basis in conjunction with US FDA changes to the drugs, clinical research, and recommendations by professional organizations, State and Federal mandates, and Standards of Medical Care guidelines.

- There are a variety of ways criteria for a drug may change. Some of these changes include:
 - Stricter criteria guidelines due to safety and efficacy concerns based on US FDA decisions.
 - Changes to a preferred version of a drug class or change to a non-preferred drug.
 - Changes to the indications (diagnoses) for which a drug is approved.
 - Changes to allowable dosages and frequencies of drugs.
 - Additional criteria based on Standards of Care for review. (i.e., conservative treatments added that must be tried by the patient first before starting the infusion drug regimen.)

Approval Process for Drug Infusion Claims

- Drug infusion approvals change from year to year and the decision is based on the criteria that is active at time of claim receipt.
- Although a majority of the reviews of drugs are approved for criteria met by a clinical reviewer (RN), if criteria is not met, the records are sent for further review by a Medical Director to determine Medical Necessity or determine if exception is warranted.
- If there remains questions on approval at this point or if a denial determination is made the next step is to have a Peer to Peer review set up with the prescribing physician.

When the records were first reviewed by our clinical reviewer, a positive determination could not be made because the insured is getting double the FDA approved dosing for both Entyvio and Remicade. Additionally, the insured is prescribed to receive both of these drugs in tandem and that is not allowed per criteria for both drug manufacturers. At this point, we requested that United refer this for review by their Medical Director, which they did. The Medical Director agreed that the drug infusions as prescribed were outside of the currently established FDA and manufacturer guidelines. However, since the treat regime was so unique and being prescribed by a Mayo clinician, it was determined that we would defer

any decision at this time and set up a peer to peer review with the prescribing physician. This review took place late Wednesday afternoon. Based on that peer to peer review, the United reviewer determined after speaking to Dr. Loftus, it is medically necessary for this member to receive Entyvio and Remicade together as a treatment. However, they also collectively determined that the current dosage is still not appropriate and that it is appropriate for them to receive the following doses as per FDA guidelines: For Entyvio, 300mg every 8 weeks; for Remicade, 5mg per kg every 8 weeks. Based on this determination, we will cover this treatment next year but at the reduced dosage and Dr. Loftus will work with the patient to start titrating them down to a normal dose range.

As an aside, below are the credentials of our Medical Director.

After your review of the preceding, should you have any questions or the need for additional information, please do not hesitate to contact me.

Thanks

Dave

Reviewer Code: 4206

Reviewer Curriculum Vitae:

This physician reviewer is board certified by the American Board of Internal Medicine in General Internal Medicine and Gastroenterology as well as by the American Board of Pediatrics in General Pediatrics. This physician reviewer is a member of the American Gastroenterological Association, the American Society for Gastrointestinal Endoscopy, the American College of Gastroenterology and the Crohns and Colitis Foundation. This physician has been in active practice since 2006.



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